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10/535,500	05/26/2006	Anne Mette Buhl Hertz	55320.001041	7327

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EXAMINER	
GUSSOW, ANNE	
ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,500	HERTZ ET AL.	
	Examiner	Art Unit	
	Anne M. Gussow	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-48,50-57 and 61-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-48,50-57 and 61-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 43-45 have been amended.

2. Claims 1-42, 49, and 58-60 have been cancelled.

3. Claims 43-48, 50-57, and 61-66 are under examination.

4. The following office action contains NEW GROUNDS of Rejection.

Objections Maintained

5. The objection to claim 50 as being of improper dependent form for failing to further limit a previous claim is maintained. Applicant's arguments filed November 5, 2009 have been fully considered but they are not persuasive. The response states that alignment of the sequence contained in SEQ ID NO 13 to all the sequences in claim 50 reveals that SEQ ID NO 13 (Exon 1) is present all of the sequences SEQ NO 11, SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 10. Therefore the detection of all of these sequences recited in claim 50 is correct as it is a subgenus of the sequences recited in the independent claims from which it depends (see response page 6).

In response to this argument, it is not clear if SEQ ID No. 13 is present in SEQ ID Nos. 10 and 11. Applicant has cited sequence alignment data that has not been provided on the record. Figure 9 graphically depicts the alignment of the sequences in

the instant application. In figure 9 it appears that neither SEQ ID Nos. 10 nor 11 include Exon 1 (SEQ ID No. 13) since they begin just before the coding sequence of SEQ ID No. 17. Additionally, the description of the sequences on pages 6-8 of the specification describe SEQ ID No. 10 as comprising two exons, exon 1 from SEQ ID No. 6 and exon 2 and 3 from SEQ ID No. 6 and 7, respectively (see page 7 lines 10-15) and SEQ ID No. 11 as comprising one exon which includes the exons 2 and 3 from SEQ ID No. 7 (see page 7 lines 16-20). Thus, it is not clear whether that SEQ ID No. 13 is encompassed by either of SEQ ID Nos. 10 and 11 and absent specific sequence alignment data it appears that SEQ ID No. 13 is not contained in each of the sequences claimed in claim 50.

Therefore after a fresh consideration of the claims and the evidence provided the objection is maintained.

Rejections Maintained/ NEW GROUNDS of Rejection

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 43-48 and 50-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The response filed November 5, 2009 has introduced NEW MATTER into the claims. Amended claims 43-45 recites "the transcribed sequence of the cDNA sequence set forth in" when describing SEQ ID Nos. 13, 15, 16, and 17. The response pointed to page 7 lines 24-43 in the originally filed disclosure for support of the claim amendment. Lines 24-43 on page 7 define SEQ ID Nos. 13, 15, and 16 as exon sequences and SEQ ID No. 17 as a coding sequence. While it is noted in this region that these exons and coding sequence are transcribed from human 12q21-22, there is no indication that these sequences are cDNAs, nor what the cDNA sequence corresponding to these DNA pieces would be since the exon or coding sequence would not be transcribed without additional mRNA (cDNA) sequence surrounding the exon or coding sequence. SEQ ID Nos. 2, 4, and 6-11 are listed as cDNAs in the instant specification. In view of this, if SEQ ID Nos. 13, 15, 16, and 17 were intended to be cDNA sequences, they most likely would have been labeled as such when the instant specification was filed. Instant claims 43-45 now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in claims 43-45, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in present claims 43-45 in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

8. The rejection of claims 43-48, 50-57, and 61-66 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

Applicant's arguments filed November 5, 2009 have been fully considered but they are not persuasive. The response states that it is clear from the wording of the claim, using the term transcriptional product, and the recitation of detected RNA sequences that the subject matter of the claims is not directed to the detection of genomic DNA in diagnosing B-CLL. The specification clearly teaches that the subject matter of the invention concerns detection of at least one transcriptional product., i.e., in the present instance specific RNA transcripts. In this regard it is clear from the specification that whereas the sequences that the SEQ ID NOs. 13 and 15-17 are cDNA (corresponding DNA) sequences that the disclosed assays in fact detect the RNA transcripts corresponding to the cDNA sequences as these transcripts are only expressed in subjects with the subject virulent subtype of CLL. (See response pages 7-13).

In response to this argument, firstly to clarify the record regarding the sequence alignment – on page 2 paragraph 4 of the previous office action mailed May 5, 2009 it states that the sequences are overlapping transcripts in a genomic region that is only transcribed in B-CLL patients with poor prognosis. There is no mention of the specific sequences, particularly SEQ ID No. 11. The examiner has not identified SEQ ID No. 11 as the primary transcript from this region based on the alignment data in Figure 9.

Further, the examiner would not have used SEQ ID No. 11 as the primary sequence to align the other sequences of the invention again based on the alignments in figure 9.

Regarding the detection of cDNA, the amended claims require the detection of transcription from a genomic region to diagnose a poor prognosis of B-CLL. SEQ ID Nos. 2, 4, 6, 7, 10, and 11 are mRNA sequences transcribed from this region. SEQ ID Nos. 13, 15, 16, and 17 are defined as exon or coding regions within this genomic region. Detection of SEQ ID Nos. 13, 15, 16, and/or 17 would not result in the population of the method (those with a poor prognosis of B-CLL) because detection of these sequences would detect the genomic copies of the DNA. All individuals would have SEQ ID Nos. 13, 15, 16, and 17 and would thus all have a poor prognosis of B-CLL if detected according to the method. Further, as set forth above the specification as filed does not define SEQ ID Nos. 13, 15, 16, or 17 as cDNA sequences, therefore the detection of SEQ ID Nos. 13, 15, 16, or 17 while encompassing the detection of mRNAs or cDNAs comprising the sequences of SEQ ID Nos. 13, 15, 16, or 17, would also encompass the detection of the genomic DNA SEQ ID Nos. 13, 15, 16, and 17 that are a part of the genomic sequence SEQ ID Nos. 1 and 5.

Regarding the detection of only SEQ ID No. 13, 15, 16, and 17, the examiner agrees that the detection of mRNA comprising SEQ ID Nos. 13, 15, 16 and 17 would include a number of different mRNA species (and corresponding cDNA species), for example SEQ ID Nos. 2, 4, 6, 7, 10, and 11. However, the claim recites detecting the presence of a transcription product, not detecting an mRNA sequence comprising... Therefore the issue is whether SEQ ID Nos. 13, 15, 16, and 17 are transcription

products. For the reasons set forth above it appears that the specific sequences of SEQ ID Nos. 13, 15, 16, and 17 without any additional sequence, are not themselves transcription products. Thus, there is insufficient evidence or nexus that would lead the skilled artisan to predict the ability to diagnose a poor prognosis of B-CLL by detecting SEQ ID Nos. 13, 15, 16, and/or 17.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
January 11, 2010

/Anne M. Gussow/
Examiner, Art Unit 1643

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643